DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

M3887n

WARNING LETTER

June 23, 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

REF: NYK-2000-79

Allen Rothpearl, M.D.
Radiologist
Central Diagnostic Imaging
37-08 28th Avenue
Astoria, NY 11103

Facility ID: 222985

Dear Dr. Rothpearl:

Your facility was inspected on June 6, 2000 by a representative of the New York City Bureau of Radiological Health, acting in behalf of the Food and Drug Administration. This inspection revealed a serious regulatory problem involving the mammography at your facility. Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 finding at your facility:

> ***The system to communicate results is not adequate because there is no system in place to communicate serious or highly suggestive cases as soon as possible.***

The specific problem noted above appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection. This problem is identified as Level 1 because it identifies a failure to meet a significant MQSA requirement.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facilities, they represent violations of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

There were also Level 2 findings that were listed on the inspection report provided at the close of the inspection. The Level 2 findings were:

- ***Eight of ten random reports reviewed did not contain an assessment category.***

- ***The phantom QC is not adequate for the Lorad Medical Systems MIII x-ray unit because the operating level for background density was < 1.20 on 5/2/00, 5/9/00 and 5/23/00.***

It is necessary for you to act on these matters immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct the violation noted in this letter;

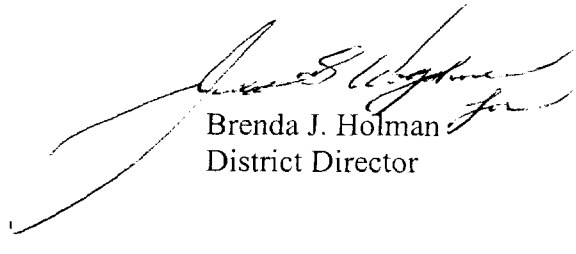
- each step your facility is taking to prevent the recurrence of similar violations; and

- sample records that demonstrate proper record keeping procedures.

Please submit your response to the above issues to the attention of Lillian C. Aveta, Compliance Officer, U.S. Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, NY 11433.

Finally, you should understand there are many FDA requirements pertaining to mammography. This letter pertains only to findings of our inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, Maryland 21045-6057 (1-800-838-7715), or through the Internet at http://www.fda.gov.

Sincerely yours,



Brenda J. Holman
District Director